

Animal Research Ethics - Policy & Procedures

1.0 Purpose

- 1.1 AUIB utilizes animals in research to comprehensively explore biological systems that are inherently complex and cannot be adequately modeled by alternative methods. Additionally, AUIB employs animal models to simulate and understand physiological responses relevant to human biology.
- 1.2 As the modeling of complex biological systems advances, the availability of non-animal subjects for significant research increases. It is an essential ethical rule, supported by laws in Iraq, that alternatives to animal testing should be adopted when they provide reliable results.
- 1.3 Animals are used in research at AUIB for two (2) purposes:
 - 1) To study standard physiological systems. This includes examining how they function normally, how they react to changes in their surroundings, and how disruptions in these systems can lead to illnesses.
 - 2) To explore disease or abnormal states. The focus is on whether these states can be reversed or slowed down through treatments that might be developed into new therapies.
- 1.4 The use of animals in research and in testing is a controversial ethical and political issue.
- 1.5 Those using animals should employ the most humane methods on the smallest number of appropriate animals required to obtain valid information.

2.0 Scope

- 2.1 This policy applies to all AUIB faculty, staff, and researchers involved in the care and use of animals for scientific purposes.

3.0 Definitions

- 3.1 Animal - any vertebrate (i.e., with a backbone) except humans, or any cephalopod species (octopus, squid, cuttlefish and nautilus).
- 3.2 Ethical review - refers to a systematic and comprehensive evaluation process conducted by an institutional ethics committee or review board to assess the ethical considerations and implications of proposed research involving human participants, animals, or sensitive data.
- 3.3 Distress - a condition where an animal is unable to avoid or adjust to external or internal stressors, leading to adverse impacts on its well-being. This differs from stress, which is a physiological response that may result in an adaptive change.

3.4 Institutional Review Board (IRB) - an independent and formally constituted committee or board established by an academic institution, research organization, or medical facility to oversee and evaluate the ethical aspects of research involving human participants or animals.

3.5 Researcher - refers to an individual or group of individuals, including scientists, investigators, academics, students, and research personnel, who are actively engaged in planning, designing, conducting, or supervising research activities involving animals.

3.6 Pain - any procedure that would likely cause more than slight or brief suffering or distress in a human to whom the procedure is applied. This includes pain that exceeds that caused by injections or other minor procedures. Pain may be either acute, lasting a short time, or chronic, persisting over a longer period. The signs of acute or chronic pain can vary and may differ between species. Prey animals are often skilled at concealing signs of pain or illness, making it challenging to detect their discomfort.

3.6.1 Signs of acute pain in animals include:

- Vocalization
- Attempts to escape the source of pain
- Aggressive behavior
- Increased heart and respiratory rates
- Refusal to eat or shaking

3.6.2 Signs of chronic pain in animals include:

- Weight loss
- Deteriorated or unkempt appearance of fur
- Signs of depression, anxiety, or lethargy
- Overall weakening and health decline

4.0 Policy

4.1 Promote the use of alternative methods to animal research whenever possible, seeking to replace animal models with non-animal techniques, such as in vitro studies or computer simulations.

4.2 Prioritize the welfare of animals, providing appropriate housing, nutrition, and veterinary care to ensure their health and to minimize stress.

4.3 Require that animal research be scientifically justified, with clear research objectives, and ensure that potential benefits far outweigh the potential harm to animals.

4.4 To enhance animal welfare and reduce suffering, AUIB will adopt the "3Rs" strategy, which includes:

4.4.1 Replacement of animals with alternative research methods whenever feasible.

4.4.2 Reduction in the number of animals used, ensuring it is the minimum required to achieve reliable results. This involves a thorough review of existing scientific literature to prevent duplicative experiments and careful planning and statistical analysis of new studies.

4.4.3 Refinement of procedures to ensure minimal harm while gathering scientific data.

4.5 The ethical review process acts as a central hub for the dissemination of best practice in the 3Rs within AUIB, so that an advance made by one individual or group can be swiftly adopted by as many others as possible.

4.5.1 During the review process, the committee examines the research protocol, experimental procedures, potential harm or distress to animals, and justification for using animals in the study.

5.0 Procedures

5.1 All proposals or study plans involving the use of animals must be reviewed by the AUIB Institutional Review Board (IRB) to assess if they are essential for acquiring new knowledge or imparting skills or concepts that cannot be learned otherwise.

5.2 The IRB evaluates animal care and use protocols/study plans to ensure:

- The necessity of using animals to meet the stated objectives,
- The minimization of pain and distress, and
- Compliance with applicable laws and ethical standards in the use of animals.

5.2.1 The IRB offers critical feedback to researchers regarding their animal research proposals. This feedback focuses on improving ethical considerations, scientific rigor, and animal welfare in their studies.

5.2.2 Researchers are required to carefully consider and incorporate the IRB's feedback into their proposals before resubmitting for final approval.

5.3 All personnel who handle animals must receive training in proper handling techniques, and it must be documented that they are proficient in any experimental procedures they perform.

5.3.1 The training must be documented in the personal training file of the individual and must be dated prior to any activity related to animal handling.

5.3.2 Basic husbandry requirements, which include providing optimal food, water, and shelter for animals, must be documented in writing and regularly reviewed to ensure compliance.

5.3.3 The checks must also be documented in writing, dated, and signed.

5.4 At AUIB, the concept of the "3Rs" is used when thinking about alternatives to animal use in research.

5.5 Any AUIB faculty or researcher using animals that may experience more than momentary pain or distress should apply the "3Rs" principle during procedures that could cause pain or distress.



- 5.5.1 Replacing vertebrate animals in research with alternative methods is a viable option, including:
- Computer modeling or in vitro testing,
 - Using "lower" or non-vertebrate animals, such as fruit flies in certain cases instead of higher-order animals.
- 5.5.2 Reducing the number of animals used in research is a critical aspect:
- This can be achieved through careful experimental design and statistical analysis. Using too few animals might lead to statistically unreliable results, potentially requiring more animals in follow-up studies.
 - Conducting pilot studies can help in determining statistical parameters and thus aid in deciding appropriate group sizes.
 - Sometimes, reducing pain and distress might necessitate using more animals to avoid repeating procedures on the same animal.
- 5.5.3 Refinement involves techniques that reduce the pain and distress experienced by animals required for experiments:
- This can be achieved using pain management strategies such as anesthetics and analgesics, as well as by providing environmental enrichment.
 - Implementing early endpoints is another method of refinement. For example, the appearance of an early disease symptom or a tumor reaching a predefined size could serve as a signal to conclude the experiment.
 - At such endpoints, animals should be humanely euthanized rather than allowing them to continue suffering until natural death.
- 5.6 Once the IRB is satisfied that the research proposal adequately addresses ethical concerns and complies with regulatory requirements, it grants formal approval for the research to proceed.
- 5.6.1 It is essential for researchers to obtain IRB approval before initiating any animal research activities to ensure that the study is conducted ethically and responsibly.
- 5.6.2 IRB approval signifies that the proposed research has met the necessary ethical standards and is deemed ethically acceptable for implementation.
- 5.6.3 The IRB may conduct periodic reviews or audits to assess the implementation of the approved research protocols and to verify that animal welfare and ethical considerations are maintained.

Related Policies and Documents

Research Policy

Research and Scholarship Integrity Policy

Research Records Management Guidelines